UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,091	05/06/2005	Juha-Matti Savola	TUR-168	2654

32954 7590 05/12/2008

JAMES C. LYDON
100 DAINGERFIELD ROAD
SUITE 100
ALEXANDRIA, VA 22314

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,091	SAVOLA ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-29,31 and 32* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/19/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/19/08 has been entered.

The response filed **2/19/08** presents remarks and arguments to the office action mailed **11/16/07**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims

Claims 23-32 are pending and examined in this office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 2/19/08 is acknowledged and has been reviewed.

Claim Objections

Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

New Claim Rejections - 35 USC § 103

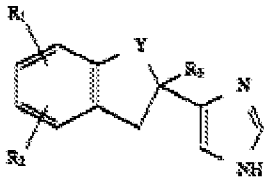
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

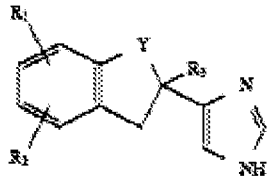
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23-29 and 31-32 remain and are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Karjalainen et al. US 5,498,623 taken with Geerts et al et al. US 5,658,938 in view of Chauveaux et al. US 6,326,401 and Huupponen et al. Clinical Pharmacol. Ther 1995;58:506-511 (applicants prior art submission) (all of record) and Smith et al., US 2004/0236108 (newly added).

Karjalain et al. teach the claimed compound as in current claim

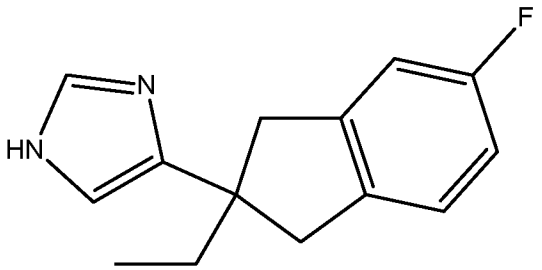


11 which is identical to the claimed compound of the claimed

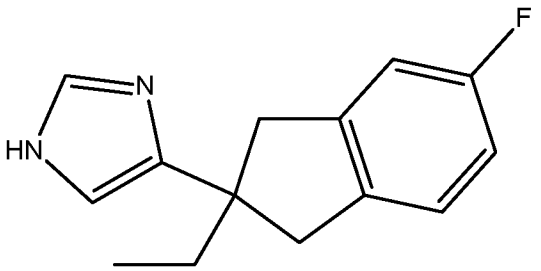


invention , wherein Y is CH_2 or CO, R_1 is a halogen or hydroxyl, R_2 is hydrogen or halogen and R_3 is hydrogen or lower alkyl-methyl (see abstract in a pharmaceutical composition administered orally (see abstract and also see col. 4, lines 62-63). Mucosal administration is a moist tissue lining such as the mouth, stomach intestines and respiratory tract. Thus administration of the composition orally is via mucosal.

With regards to claims 24 and 25 the reference teaches (see abstract



also) 4-(2-ethyl-5-fluoro-2,3-dihydro 1H indan-2-yl)-1H-imidazole is the same as



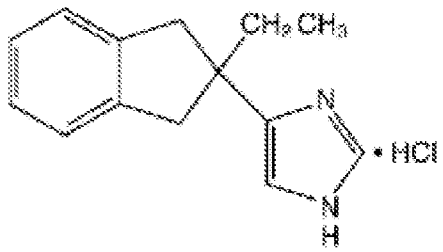
4-(2-ethyl-5-fluoro- indan-2-yl)-1H-imidazole or its salts. As to the hydrochloride salt of the said formula the reference teaches the preparation of such salt (see col. 7, lines 48-50).

Karjalainen et al. is applied here as above, to instant claims 11-13. The reference also teaches with regard to ethanol as the solvent as required by instant claims 15 and 27. See col. 7, lines 63-64.

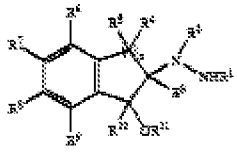
The Geerts et al. teach an imidazole compound (see abstract) wherein the composition comprises flavoring-thus interpreted as sweetening agents as in the instant claim 14 and the solvent is water (see col. 11, lines 16-20) as in claims 14-15 and 27. Known flavoring agents are lactose, aspartame glucose etc. One of ordinary skill in the art would have been motivated to use a common flavoring agent and it is within the skill artisan to choose. Thus obvious variation of the types of flavors.

Even though the above references did not teach the addition of a preservative to the composition. However, the Chauveaux et al. teach, the use of methyl and propyl parahydroxyybenzoate in an oramucosal formulation (see col. 3, lines 36-45) as required by instant claims 11, 16, 26 and 28.

Huupponen et al. teach antipamezole hydrochloride (see abstract) a drug that is within the core structure of the claimed compound



, wherein the solvent is water and alcohol-thus mixture thereof is within the claim limitation (see page 506, sec methods under heading and also page 507, under drug administration) as in the instant claim 15, in a form of spray (wherein one to four shots were given from bottles with atomizer designed to deliver…) (see lines 8-10 under drug administration, pg 507) as in claims 19-20 and 31-32. The reference also teaches the drug is oromucosal (see pg, 506, rt. col. four lines from the bottom).

Smith et al. teach administering a core structure of the instantly claimed compound  see abstract. The compound is administered oromucosally see para 0079.

Smith teaches this class of compounds are administered oromucosally and that the administration is based

One of ordinary skill in the art would have been motivated to make an oromucosal formulation of the above compound with a preservative because the Chauveaux et al. teach the composition of that comprises a preservative taken with the teaching of Smith one of ordinary skill would be motivated to form an oromucosal formulation for administration. The addition of the preservative is for preserving the homogenous formulation as taught in col. 3, lines 39-42. Thus one of ordinary skill in the art would have been motivated to incorporate the addition of a preservative in the formulation.

Also, the cited references did not teach a particular favoring to the composition, however, one of ordinary skill in the art would have added flavorings to the composition to improve on its taste and especially used black currant because it does not only gives flavor it also adds color that is appealing particular to kids. Thus one of ordinary skill in /the art would be motivated to use a flavor that will give both taste and color to the drug that is used for oromucosal administration.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
4/29/08

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614